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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,772	07/31/2002	Malcolm Roy Brandon	78870/00004	7473

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TUCKER ELLIS & WEST LLP
1150 HUNTINGTON BUILDING
925 EUCLID AVENUE
CLEVELAND, OH 44115-1414

EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	
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08/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,772	BRANDON ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 17, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9-15,20-23,30,34-36 and 41-43* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 9-15, 20-23, 30, 34-36 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments filed May 17, 2007 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-4, 6, 7, 9-23, 30-36 and 41-43 are pending. Claims 16-19 and 31-33 are withdrawn from consideration as to a nonelected invention. Claims 1-4, 6, 7, 9-15, 20-23, 30, 34-36 and 41-43 are examined herein.

The rejection of claims 1, 11, 30, 34 and 37-40 under 35 U.S.C. § 112, second paragraph in the office action mailed February 28, 2007 is withdrawn in view of amendments to the claims.

The rejection of claims 37-40 under 35 U.S.C. § 102 (b), or in the alternative, under 35 U.S.C. § 103 in the office action mailed February 28, 2007 has been withdrawn in view of the cancellation of these claims.

The rejection of claims 1, 2, 4, 7, 10-13, 20, 21, 30, 34, 36 and 41-43 under 35 U.S.C. § 102 or 35 U.S.C. § 103 in the office action mailed February 28, 2007 is withdrawn in view of amendments to the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7, 9-15, 20-23, 30, 34-36 and 41-43 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of preparing a reprogrammed diploid mammalian cell comprising providing a diploid mammalian donor cell or a diploid mammalian donor nucleus and a recipient mammalian oocyte, microinjecting the donor nucleus into the oocyte, removal of the oocyte nucleus, incubation of the reconstructed oocyte, activation of the oocyte to permit develop into embryos, as claimed does not reasonably provide enablement for methods of preparing a reprogrammed diploid mammalian cell from non-mammalian cells or non-mammalian nuclei

through the use of a non-mammalian recipient cell, or the production of a mammal, mammalian organs or tissues or animals by the claimed methods for reasons set forth in the office action mailed February 28, 2007. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are unpredictable as written as to make a reprogrammed mammalian cell or embryo mammalian donor and recipient cells would need to be used. The use of other species cells would not result in a mammalian cell or embryo. Further, there would necessarily need to be a means to determine the recipient and donor nuclei in the claimed method. The specification only discusses one method of doing such, which is the piezo-impact microinjection system (Wakayama (1998), page 373, col. 2, lines 5-12 and specification, page 30, line 28 to page 31, line 1; and page 33, lines 15-20). The specification provides no other guidance for identifying donor and recipient nuclei. The guidance provided in the specification, is for the microinjection of the donor nucleus followed by immediate removal of the recipient nucleus (specification, page 33, lines 15-27). The now diploid reconstructed oocyte is incubated 3-4 hrs prior to activation and embryo development permitted.

Applicant argues Pennisi and Vogel are not relevant because the present invention is to nuclear addition, not nuclear transfer. Applicant further argues nuclear addition has benefits to reprogramming not present in nuclear transfer. These arguments are not persuasive.

Nuclear addition or oocyte nucleus removal after nuclear transfer is variations on the theme of nuclear transfer. While the method of the claims was not known in the art prior to applicant's filing date, the enablement issues are the same regardless of when the nucleus is removed. Pennisi discussed the failure of nuclear transfer in several mammalian species.

Applicant has not provided any evidence or argument as to why oocyte enucleation after transfer of the donor nucleus would have any bearing on Pennisi's teachings. It is noted that the specification discloses the production of chimeric mouse tissues and organs. However, the claims are not limited to chimeric mice or their organs or tissues. While applicant has provided evidence that their method produces a greater number of blastocysts using pig donor cells and oocytes (Table 1, page 36), there is no evidence that a greater number of pig blastocysts yield a greater number of cloned pigs. Similar data could not be found for mouse. The pig data provided does not overcome Pennisi that clearly states even pregnancy does not assure term deliver of a cloned mammal.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9, 20-23 and 30 are confusing rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is confusing as they broaden the scope of claim 1. Claim 1. Claim 7 states the donor cell states the donor cell or donor nucleus is a somatic cell or a somatic cell nucleus as being an embryonic cell or an embryonic cell nucleus.

Claim 9 is confusing as it does not further limit claim 1, which states the donor cell or donor nucleus is a somatic cell or a somatic cell nucleus.

Claims 20-23 remain improperly dependent on claim 1 for reasons set forth in the office action mailed February 28, 2007. Claim 1 is to a method of preparing a reprogrammed diploid mammalian cell. Claims 20-22 are further comprising the step of generating a cell line, a tissue, an organ or an animal embryo from the reprogrammed cell. Claims 20-23 are not related to a method of reprogramming a cell, but are in fact to

methods of using the reprogrammed cell to produce products. Claims 20-22 should be rewritten as independent claims. However, applicant is warned that doing such may result in a restriction by original presentation.

Applicant argues the Federal Circuit, 2 USPQ2d 1826, stated in an independent claim is unobvious then claims, which are dependent upon the independent claims are unobvious. This argument is not persuasive.

While the Federal Circuit did state this, the relevance to present rejection is not clear. There is no issue of obviousness here, but whether or not claims 20-23 further limit claim 1. Claims 20-23 cannot further limit claim 1 as they are to a use for the reprogrammed cell of claim 1. Claim 20 is a method of generating a cell line, tissue, organ or transgenic mammalian embryo from the reprogrammed cell produced by claim 1, claim 21 is to a method of generating a non-human mammal from the reprogrammed cell produced by claim 1. Claim 23 is to a method a method of producing a nonhuman transgenic mammal using the reprogrammed cell produced by the method of claim 1. These methods have nothing to do with reprogramming a donor somatic cell or an isolated donor somatic cell nucleus. None of claims 20-23 affect the reprogramming method. Therefore claims 20-23 do not further limited. As stated previously, applicant should write the subject matter in claims 20-23 as independent claims.

Claim 30 is confusing as to the terms "animal" in the preamble and line 13. This is broader in scope than "mammal" as other parts of the claim was amended to contain.

The claims are free of the prior art. At the time of filing the prior art did not teach or suggest methods of preparing a reprogrammed diploid mammalian cell comprising providing a diploid mammalian donor somatic cell or a diploid mammalian donor somatic cell nucleus and a recipient cell, introducing the donor nucleus into the cell, subsequent removal of the

oocyte nucleus, incubation of the reconstructed oocyte, and optional activation of the oocyte to permit develop into embryos.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

July 27, 2007